IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION MDL No. 2327

THIS DOCUMENT RELATES TO:

Cases Identified in the Exhibit
Attached Hereto

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Peggy Pence, Ph.D.)

Pending before the court is the Motion to Exclude Peggy Pence, Ph.D. [ECF No. 2075] filed by the defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon"). The Motion is now ripe for consideration because briefing is complete.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 30,000 of which are in this MDL.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict Litigation in Products Liability Cases* 3 (2011). To handle motions to exclude or to

limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order ("PTO") No. 217, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion. PTO No. 217, at 4.[1]

II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties' misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert*'s core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations

[1] Ethicon identified the Wave 1 cases affected by this Motion in its attached Exhibit A [ECF No. 2075-1], which the court has attached to this Memorandum Opinion and Order. At the time of transfer or remand, the parties will be required to designate relevant pleadings from MDL 2327, including the motion, supporting memorandum, response, reply, and exhibits referenced herein.

to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[ ] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of the expert testimony may be evaluated at trial. At trial, the expert testimony will be tested by

precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of "junk science" looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court's prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—I will therefore reserve ruling until expert testimony can be evaluated firsthand.

III. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

> (1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts "principles and methodology" above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g.*, *Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

IV. Discussion

Dr. Pence has a Ph.D. in toxicology and holds herself out as a specialist in medical device product development, regulatory affairs, and labeling standards. She intends to testify on behalf of the plaintiffs but Ethicon seeks exclusion of her

opinions.

a. Warnings

Ethicon claims Dr. Pence is not qualified to offer expert testimony about the adequacy of the relevant Instructions for Use ("IFU"). I disagree. Dr. Pence has over forty years of experience in the research and development of medical devices, and she has accumulated knowledge about the content of product labeling. Accordingly, Ethicon's motion is **DENIED** on this point.

Ethicon claims Dr. Pence's expert testimony is not reliable because she never spoke to any physicians about labeling and their knowledge. But an expert's failure to examine a particular source of information is not grounds for exclusion under *Daubert* if the expert testimony is supported by other "sufficient facts or data." Fed. R. Evid. 702. Dr. Pence considered, for example, medical and scientific literature, the relevant IFUs, and internal Ethicon documents. This collection of sources is sufficient for the purposes of *Daubert*. Ethicon may attempt to expose any perceived shortcomings through cross-examination. Accordingly, Ethicon's Motion is **DENIED** on this point.

Relatedly, Ethicon argues that Dr. Pence cannot offer expert testimony about whether the relevant IFUs "are adequate for doctors to obtain informed consent of their patients" because she is not qualified and because her expert testimony is unreliable and irrelevant. Mem. Supp. Pence Mot. 14 [ECF No. 2078]. Because application of the informed consent doctrine turns on the applicable state law, I **RESERVE** ruling on this matter.

b. Premarket Testing

Ethicon claims Dr. Pence is not qualified to offer expert testimony about premarket testing of medical devices. Dr. Pence has over forty years of experience in the research and development of medical devices. Over that time, she has accumulated knowledge about the clinical testing of novel medical devices. So Ethicon's Motion is **DENED** on this point.

Ethicon claims Dr. Pence's expert testimony is not reliable because she does not apply the standards on which she relies to determine whether Ethicon met those testing standards. In my view, the plaintiffs do not respond to this argument. However, the plaintiffs respond that Dr. Pence's expert testimony is reliable because it is also based on her experience. As a result, the reliability inquiry must probe into the relationship between the experience and the expert testimony. *Cf.* Fed. R. Evid. 702 advisory committee's note to 2000 amendment ("If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts."). In this context, I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony on premarket testing. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

c. Market Removal

Ethicon asks the court to exclude Dr. Pence's opinion that Prosima should have been removed from the market before it was actually removed from the market and,

by failing to do so, Ethicon violated its commitment to patient safety. Most problematic is Dr. Pence's reliance on Ethicon's "[c]redo of putting doctors and patients first." Pence Rep. 49 [ECF No. 2075-5]. Liability is not predicated on a company's compliance with its own credos or codes; liability is instead predicated on the legal standards of the case. *See, e.g.*, *Restatement (Third) of Torts: Physical & Emotional Harm* § 13 cmt. f (Am. Law Inst. 2010). Accordingly, expert testimony of this sort is not helpful to the jury and is thus unreliable and **EXCLUDED**.

V. Recurring Issues

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re*

C. R. Bard, 81 F.3d at 920 ("[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value."). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors "to erroneously conclude that regulatory compliance proved safety." *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon's compliance with design control and risk management standards. Some of this testimony involves the FDA's quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a

product's risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing, where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here.

First, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *E.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony."). Additionally, an expert may not offer expert testimony using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

Second, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

Third, many of the motions also ask the court to require an expert to offer testimony consistent with that expert's deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers

inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

Fourth, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

Finally, in some of the *Daubert* motions, without identifying the specific expert testimony to be exclude, the parties ask the court to prevent experts from offering other expert testimony that the moving party claims the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

VI. Conclusion

The court **DENIES in part**, **GRANTS in part**, and **RESERVES in part** the Motion to Exclude Peggy Pence, Ph.D. [ECF No. 2075].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 1 cases identified in the Exhibit attached hereto.

ENTER: August 25, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

Exhibit A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES	**Joseph R. Goodwin** **UNITED STATES DISTRICT JUDGE**

Exhibit A to Defendants' Motion to Exclude Peggy Pence, Ph.D.

List of Applicable Cases[1]

Case Name	Case Number	Product(s)
Amsden, Donna	2:12cv00960	Prolift
~~Banks~~ Smith, Marie	2:12cv01318	TVT
Boggs, Sharon & Michael	2:12cv00368	TVT-O & Prolift
Bollinger, Karen	2:12cv01215	TVT
Burkhart, Denise	2:12cv01023	TVT
Byrd, Myra & Richard	2:12cv00748	TVT-O
Carpenter, Sharon & Gardner	2:12cv00554	Prolift
Cole, Carey Beth & David	2:12cv00483	Prolift
Coleman, Angela & Timothy	2:12cv01267	TVT-O

[1] Plaintiffs' designation states that they recognize the Fourth Circuit's affirmance of this Court's exclusion of evidence of compliance with the 510(k) process and "reserve the right to designate" Dr. Pence "[i]n the event of a contrary ruling." Ex. L, Pls. General Expert Desig., p. 2. Ethicon understands this to mean that Dr. Pence is not designated at all if no FDA evidence is admitted, even though this is potentially inconsistent with Dr. Pence's current disclaimer of reliance on FDA regulations. In addition, Ethicon notes that this "reservation of right to designate" in some instances puts Plaintiffs' number of experts over the allotted five.

Collins, Fran Denise	2:12cv00931	TVT-O
Cone, Mary F.	2:12cv00261	TVT-O
Conti, Patricia	2:12cv00516	TVT
Deleon, Amanda & Raymond	2:12cv00358	Prolift
Destefano-Raston, Dina & Terry	2:12cv01299	TVT-O
Drake, Karyn E. & Douglas E.	2:12cv00747	TVT
Forester, Karen & Joel	2:12cv00486	TVT-O
Fox, Sherry & Roy, Jr.	2:12cv00878	TVT
Free, Pamela	2:12cv00423	TVT
Freeman, Shirley & William	2:12cv00490	Prolift +M
Funderburke, Betty	2:12cv00957	Prolift & TVT
Georgilakis, Teresa & Angelo	2:12cv00829	TVT-O
Gomez, Rose & Jesus	2:12-cv-00344	Prolift & TVT-O
Gray-Wheeler, Pamela	2:12cv00455	Prolift & TVT-Secur
Guinn, Susan	2:12cv01121	TVT-O
Hankins, Dawna	2:12cv00369	TVT-O
Hankins, Donna & Roger	2:12cv01011	TVT
Hendrix, Mary & Thomas	2:12cv00595	TVT
Herrera-Nevarez, Rocio	2:12cv01294	TVT-O
Hill, Barbara A. & Billy W.	2:12cv00806	Prolift
Johnson, Wilma	2:11cv00809	Gynemesh PS & TVT
Jones, Holly & Jason	2:12cv00443	TVT
Kaiser, Barbara	2:12cv00887	Prolift

Kirkpatrick, Margaret	2:12cv00746	TVT-O
Kriz, Paula & James	2:12cv00938	Gynemesh PS & TVT-O
Lehman, JoAnn	2:12cv00517	TVT-O
Long, Heather	2:12cv01275	TVT
Loustaunau, Donna	2:12cv00666	Prolift
Lozano, Deborah & Felipe	2:12cv00347	Prolift & TVT-O
McBrayer, Dee & Timothy	2:12cv00779	Prolift
Nix, Cynthia	2:12cv01278	Prolift; TVT-O
Olson, Mary Jane & Daniel	2:12cv00470	Prolift; TVT-O
Padilla, Noemi	2:12cv00567	Prolift +M
Patterson, Miranda	2:12cv00481	TVT-O
~~Pratt~~ Bartlett, Rebecca	2:12cv01273	TVT
Reyes, Jennifer & Jerry	2:12cv00939	TVT
Rhynehart, Penny	2:12cv01119	Prolift & TVT-O
Ruebel, Ana	2:12cv00663	Prolift; TVT-O
Shultis, Stacy	2:12cv00654	TVT-O
Sikes, Jennifer	2:12cv00501	TVT-O
Smith, Carrie	2:12cv00258	TVT-O
Springer, Cherise & Marty	2:12cv0997	TVT-O
Swint, Isabel	2:12cv00786	TVT-O
Teasley, Krystal	2:12cv00500	TVT-O
Thaman, Susan	2:12cv00279	Prolift; TVT-Secur
Thomas, Kimberly	2:12cv00499	Prosima; TVT-O

Thurston, Mary & Kenneth	2:12cv00505	TVT
Warlick, Cathy	2:12cv00276	Prosima; Prolift
Williams, Nancy	2:12cv00511	Prolift; TVT-O
Wiltgen, Christine & Mark S.	2:12cv01216	TVT
Wolfe, Sandra	2:12cv00335	Prolift; TVT-O

***Dr. Pence was also designated in a number of cases involving only the Gynemesh PS, Prolene Soft, or TVT-Secur products, but she did not provide an expert report for those products.**

Case Name	Case Number	Product(s)
Beach, Harriet	2:12cv00476	Gynemesh PS
Bridges, Robin	2:12cv00651	Gynemesh PS
Evans, Ida Deanne	2:12cv01225	Prolene Mesh
Fisk, Paula	2:12cv00848	Gynemesh PS
Grabowski, Louise	2:12cv00683	Gynemesh PS
Hooper, Nancy & Daniel	2:12cv00493	Gynemesh PS
Lee, Alfreda & James	2:12cv01013	TVT-Secur
Ruiz, Patricia	2:12cv~~00470~~1021	TVT-Secur
Tyler, Patricia	2:12cv00469	Prolene Soft

*** Defendants reserve the right to supplement this list should any plaintiff designate Dr. Pence as a general expert in MDL Wave 1.**